

**Summary Report of
First Meeting of the
Working Group on Risk Analysis
of the OIE Region for the Americas**

**August 23 - 27, 1999.
Fort Collins, Colorado
OIE Collaborating Center**

As an outcome of this initial meeting, we are moving in the following direction:

1) We have formed an ongoing Regional Working Group to develop common agreements and interpretations that will form the basis of the manual. The first meeting of the Regional Working Group focused on overall aspects of the analysis process, key definitions, key Spanish/English vocabulary, and setting functional norms. The second meeting (Feb 28 - March 3) will focus on the likelihood of “release” and “exposure” assessments (Code articles: 1.4.2.4.1 and 1.4.2.4.2). *(A list of the Regional Working Group objectives and operating plan is contained in Appendix C and D).*

2) We have begun to use these agreements to develop a “manual” for the Americas which can accompany the existing Code chapter on Risk Analysis. The manual will form the basis of understandings, methods and practices that are recommended by the OIE Region for the Americas. The manual would be accompanied by a set of recommended “best practices.” These will consist of risk analyses done by member countries and others, theoretical and practical articles, and other materials. *(An early draft of agreements from the first meeting is found in Appendix A).*

The manual and best practices would be available on a Web site maintained by CEAH as an OIE Collaborating Center.

3) In addition to the manual, we have begun to develop a set of recommendations for revisions in the Code. These recommendations reflect implications for the use of risk analysis which go beyond the region. *(An early draft of recommendations is found in Appendix B).*

4) We have developed the outline of a training plan. The primary emphasis in this plan is on the development of materials based on the above “manual” which can be used throughout the Americas on a regional or individual country level. We propose a variety of ways in which these materials can be used in courses and training events. In addition, the Regional Working Group generated some ideas and observations which would be useful for looking at “Evaluation of Veterinary Services.” *(An early draft of this plan is found in Appendix C).*

5) The results of the Regional Working Group will be forwarded annually to the meetings of the OIE Region of the Americas for their consideration and, hopefully, ratification.

**Appendix A. Regional Working Group on Risk Analysis
Points of Clarification and Agreement**

The Interim Manual for the Region of the Americas			
OIE Code	Problem or Question	Clarification for Region of the Americas	Reference / Tools
1.4.2.1. Introduction	Do the guidelines apply to import commodities only?	<p>These guidelines are intended to be used in conjunction with risk analyses for the importation of commodities from one country or region to another. The methods which are referenced are applicable to risk analysis of import commodities.</p> <p>Risk analysis is a broad field of study. Within risk analysis, tools and methods have been developed to meet specialized issues. These guidelines are not intended to be utilized with other forms of risk analysis, such as those applied to recognizing the disease status of zones or regions, or evaluating monitoring and surveillance systems.</p>	
	Why is “probable annual quantity” of the import significant?	The term “quantity” should not be interpreted as reflecting a quota or a set amount for the risk analysis. Quantity is an inherent characteristic of an import commodity. Risk analyses need to account for a range of likely import quantities, but this range does not in any way imply that quantities of imported commodities should be limited.	
	What is the real relationship in the process between risk analysis and risk management?	Various diagrammatic models advanced by OIE member countries have contributed to further clarifying how risk assessment and risk management are integrated. As of August 1999, the Regional Working Group has drafted a diagrammatic, conceptual model for the Americas that combines ideas from these various sources (see attached diagram).	A practical, 9-step approach that countries can use to implement some portions of the conceptual model appears in the 1993 article, “Developing a quantitative risk

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	Figure 1 <i>Language note</i>	<i>The English term “commodity” is much more specific in meaning than the Spanish “mercancia.”</i>	assessment process,” by Miller and McElvaine.
1.4.2.2 Hazard Identification	What should be the scope of hazard identification, and when is a risk analysis necessary	<p>These questions are interrelated, as is the question of what administrative processes a country should use to determine when risk analysis is needed.</p> <p>No clear tool (for example, a list of specific disease agents; an administrative flow chart; or a preliminary risk assessment) has emerged as a useful method that could serve a wide range of countries or importation issues.</p>	
1.4.2.3 Principles of risk analysis	What does it mean that both qualitative and quantitative methods are <u>valid</u>?	<p>The term “qualitative” currently covers two distinct types of risk assessment. The first is descriptive in nature and the second is one which uses formal qualitative methods and techniques. It is, therefore, more appropriate to talk about three types of risk assessments, all of which may have an appropriate function. All three types have elements which may be combined appropriately in any one import commodity risk analysis.</p> <p><u>Descriptive</u> risk assessments rely upon a strong narrative relating of principle events and factors. This form of assessment may contain scientific references, references to other risk assessments, significant quantitative data, etc. Generally these present a salient description of the situation of a particular commodity vis a vis a particular country or region. The end product of this form of risk assessment is an opinion on the categorization of a level of risk (“high, medium, low, minimal, etc.”).</p> <p><u>Qualitative</u> risk assessments utilize a formal model and a large variety of methodologies found in the scientific literature. In a qualitative study, categorical, and sometimes quantitative, data are moved through the model</p>	<p>See:OPS-PANAFTOSA jose naranjo Author analisis de situacion de riesgo sanitario referente a la importacion de bovinos de razas de lidia a Colombia procedentes de Espana. Also, there are a number of country level BSE risk analyses which utilize a</p>

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Principles (cont)	What is meant by “expert opinion?”	<p>in a calculated manner. Qualitative risk assessments may include both parametric and non parametric statistics. The techniques of a qualitative risk assessment are transparent.</p> <p>The end product of a qualitative risk assessment is a calculated measure of risk. It is expressed as categorization of a level of risk. But unlike descriptive risk assessments, this end product is more than a judicious “opinion.” It is rather a measure which can be replicated under other circumstances.</p> <p><u>Quantitative</u> risk assessments rely heavily upon quantitative techniques, such as parametric and non parametric statistics, probability distributions, analysis of variance, sensitivity analysis, and other statistical methodologies. At the same time, they frequently are linked to narrative and qualitative techniques within the whole of their risk analysis. The end product of a quantitative risk assessment is frequently presented as a mathematical or statistical measure.</p> <p>Use of experts and expert opinion are intended to be a methodological tool, rather than simply a supportive personal communication. Examples of how expert opinion has been methodologically accessed include (1) requesting and evaluating independent analyses from multiple experts in a given field; or (2) convening a panel of experts who present their analyses on a given topic, followed by interactive panel discussion and recommendation of preferred methods.</p>	descriptive approach, though they do not relate to specific import commodities.
1.4.2.4.4.	Why are only the results of a quantitative	The output of descriptive and qualitative risk assessments is generally a categorization of levels of risk. The output of a quantitative risk assessment	

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Risk Estimation	risk assessment listed?	is generally expressed in numeric form. However this numeric measure is generally translated into a categorization of risk for managers within the whole analysis process.	
Risk Estimation (cont)	What is the real end point of a risk analysis?	At this point, most risk analyses end with a “recommendation” on action to be taken by the importing country. This, however, may not represent a true or final output which may actually take the form of an “annualized cost” presented by a particular risk. This annualized cost includes the likelihood and consequences of adverse events as specified in the Agreement on Sanitary and Phytosanitary Measures. Thus far there have been few risk analyses which attempt to reach this final end point. This is a challenge still facing the risk analysis community and it is unclear at this point when and if it will be met.	
	Language note		
	How does the concept of “threshold” fit into all of this?	<i>The Spanish term “suma” does not mean the English “takes into account” in describing risk estimation. Another term should be used.</i> The concept of “threshold” has been debated for a long time. There is currently no widely accepted definition. It has been conceived of as a “fixed statistical line” separating acceptable from unacceptable risk. It has also been conceived of as a “moving equilibrium” balancing acceptable vs. unacceptable risk. While the concept is critical to “yes/no” decision making, more theoretical work and its practical application need to be carried out before agreement will be reached.	
	How should risk estimation	The definition of risk includes both likelihood and magnitude of consequences. Therefore, outputs should include both consequences, and likelihood. A mix of quantitative, qualitative and/or descriptive methods may	

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	outputs be expressed?	<p>at times be appropriate to express outputs in terms of both likelihood and consequences. For example, a country may apply a quantitative approach for likelihood, combined with a narrative description of consequence, as inputs to the risk estimate output.¹ Methods may also be mixed in a release assessment.</p> <p>“Risk estimation” can be considered to be synonymous with “risk assessment output.” This clarification is intended to acknowledge that a country has reviewed both likelihood and consequence in some manner.</p>	

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**Appendix B. OIE Workshop on Risk Analysis
Recommendations for the Code Commission and
to the OIE Region of the Americas on “Evaluation of Veterinary Services”**

OIE Code		Recommendations to the OIE from the Region of the Americas
1.4.2.1. Introduction		<p>The title of this chapter 1.4.2. should be changed to “Guidelines for Risk Analysis for Import Commodities.” The fact that this chapter is then followed by ones dealing with zoning and regionalization give the impression that the methods described herein are also applied to those chapters and issues. While chapter 1.4.2 deals with risk analyses that can evaluate commodities originating from zones or regions, the risk associated with a commodity import is distinctly different from the risk of a zone or region being free of disease or not.</p> <p>The OIE Code may wish to consider developed a separate chapter or sections to this chapter on appropriate risk analysis methods for determining disease status of regions or other issues</p> <p><i>Note on usage: It may be that when importation is proposed from a country or region which has been declared “free of a disease,” a risk analysis to determine disease free status may be more appropriate than a risk analysis for a commodity import.</i></p>
		<p>The OIE Code should reconsider the use of “quantity” in the introductory section. While being an important characteristic of the import, its mention here may give it undue weight.</p>
1.4.2.3 Principles		<p>The OIE Code should discriminate between the use “in words” and the term “qualitative” which are referenced together throughout the Code chapter. The equation of verbal means of communication with qualitative methodology is inappropriate.</p> <p>The OIE may also wish to consider the Region’s division of risk assessment into three major types. Currently the code assumes that qualitative and quantitative methods fit exclusively into only two distinctive types of analyses. In fact, description, qualitative techniques and quantitative techniques may figure in any one risk assessment.</p>

Appendix B. Recommendations for the Code Commission

OIE Code		Recommendations to the OIE from the Region of the Americas
1.4.2.4.4. Outputs		The OIE Code should set out the outputs for qualitative and descriptive risk assessments. It currently appears as if only quantitative assessments have outputs.
Recommendations to the OIE Region of the Americas Group on Evaluation of Veterinary Services		
		<p>The Regional Working Group on Risk Analysis discussed the evaluation of veterinary services as an input into the risk analysis process. There is a major concern that this topic will become, in and of itself, an impediment to trade. Countries are already receiving long and obtuse questionnaires from different countries, asking for the same or for slightly different information. These questionnaires appear to have little or no understanding of the realities of most American States.</p> <p>One approach, taken by Canada, is to place relevant information on a Web site concerning their organization and functions. This generic information is, then, available to any country which wishes the information. The Canadians do not appear to be preparing to answer individually tailored questionnaires for the multitude of their actual or potential trading partners.</p> <p>One may think of evaluation data on several levels. Within the Americas, the Canadian example deals with one level of “evaluation” data. That is, what is the generic information about our organizations.</p> <p>A second level of information deals with those functions that are most closely associated with the import (and export) of animal trade commodities. These functions would be certification systems, inspection systems, etc. In many cases, these may not be carried out by Veterinary Services per se. An important task is to identify these functions and the criteria or key indicators of their successful implementation.</p> <p>A focus on functions closely related to import commodity activities would eliminate unnecessary concern with structure, bureaucratic organization, etc. It would keep evaluation data focused on the search for an “ideal” national service and more on promoting a level of trust in the key operations of actual or potential trading partners.</p>

**Appendix C. OIE Region of the Americas
Working Group on Risk Analysis**

Objectives

The Problem

Member countries of the OIE Region of the Americas are currently using many different approaches to risk analyses required for trading purposes in animals and animal products. These approaches lack a common vocabulary, conceptual base and methodological “tool kit.”

The different “realities” of member countries mean that very different sets and scales of resources are being used to develop these analyses. Further the manner in which they are utilized as a part of trade decision making is frequently unclear.

The OIE guidelines on risk analyses require clarification, interpretation, and practical directions for their implementation by member countries of the Region of the Americas.

Goal and Objectives

The goal of the working group is to harmonize approaches to risk analysis used by member countries of the Region. The potential benefits will enable member countries to improve the efficiency and transparency of decision making regarding trade in animals and animal products in accord with the SPS agreement.

More specific objectives of the working group are:

- 1) Develop a common set of terms, methods and concepts for developing and using risk analyses within the Region of the Americas ,
- 2) Promote a set of “best practices” based upon an expanding number of risk analyses and technical papers done by OIE member countries within and outside the region,
- 3) Continually update the level of knowledge and skills for using risk analyses within the Region of the Americas through training materials, seminars, etc.
- 4) Develop a network of risk analysis specialists in the Americas who can work together on an ongoing basis to harmonize approaches.

Appendix C. Regional Working Group Objectives

- a) an “interim manual” for use in the Region of the Americas which clarifies terms and concepts currently utilized in the OIE Code,
- b) a set of “best practice” examples to be used as a part of the “interim manual.” These examples would be chosen from an expanding number of risk analyses, technical papers and other sources,
- c) regular recommendations to the Region of the Americas on the use and implementation of risk analyses within the region and

When appropriate and based upon our experience in the Region, it is anticipated that recommendations made be made to the OIE Code Commission on how further clarifications to the Code may assist other member countries in the development and use of risk analyses.

All materials developed by the Working Group will be distributed in Spanish and in English. Close attention will be paid to consistency and clarification of terms in translation.

Operating Norms

The working group proposes to operate in the following manner:

- a) hold periodic meetings to clarify responses to critical problems related to the development and use of risk analyses,
- b) develop and maintain (at the Collaborating Center in Fort Collins) a web site for disseminating the “interim manual” and accompanying examples, technical papers, etc.
- c) develop regular products for discussion and possible adoption by the Region of the Americas,
- d) develop training and educational materials to foster a common approach to risk analyses in the Region of the Americas.

Appendix D. Regional Working Group Operating Plan

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Operational Plan for the Year 2000

In order to meet its objectives, the Working Group on Risk Analysis has developed the following action steps and responsibilities for the next 12 months:

1. The OIE Collaborating Center in Fort Collins would supply coordination and logistical support to the OIE Region of the Americas Working Group on Risk Analysis. This would include:
 - a) on going coordination of Regional Working Group communications. Cristobal Zepeda would act as the coordinator.
 - b) providing a Web site to assist communication among the Regional Working Group members (having limited access) and a Web site for public dissemination of results of their work. The public Web site would contain the “manual” for risk analysis, training materials, and key reference documents exemplifying “best practices.”
 - c) hosting a second meeting of the Regional Working Group on February 28 - March 3, 2000.
 2. A series of meetings of the Regional Working Group would be held in 2000 - 2001 to clarify and reach agreement on approaches to significant aspects of risk analysis. The outcomes of these meetings would form significant sections of the “manual,” designed to accompany the current Code. Each section of the manual would be accompanied by a set of completed risk analyses or assessments that set a standard for “best practices.” Theoretical or practical articles would supplement these “best practices.”
- The first meeting of the Regional Working Group focused on overall aspects of the analysis process, key definitions, and setting functional norms. The second meeting (Feb 28 - March 3) will focus on the likelihood of “release” and “exposure” assessments (Code articles: 1.4.2.4.1 and 1.4.2.4.2). The meeting will cover: a/basic concepts, b/tools and methods, and c/”best practice” examples. It will be based upon the use of computerized programs and conceptual frameworks.
3. Based upon this first meeting, the Regional Working Group will prepare a report and a set of

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Training Strategy

The role of the Regional Working Group is to develop a common approach to risk analysis for the member countries of the Americas. This approach is generated through the exchange of ideas and consensus (whenever possible) within the group. The results of its deliberations will be in the form of a “manual.” This manual will form the basis for training materials which can be utilized throughout the Americas.

The first priority of the Regional Working Group will be on the development of the common approach through a “manual” and subsequent training materials. The initial sections of the manual and training materials should be available in the second half of 2000. These materials would be disseminated through hard copy to the member countries and on a public Web site.

The members of the Regional Working Group would share responsibility for using this common approach in their work and in appropriate training opportunities. Multiple formal training programs occur through regional organizations (such as OIRSA) and through national governments throughout the year. The Regional Working Group would rely upon such venues to disseminate its common approach. In addition to face to face settings, the use of “distance learning” and other forms of educational communication will be explored.

In crafting its strategy, the Regional Working Group must first develop its common approach. It will do so through its meetings and through electronic and other forms of communication. Two target audiences for this common approach are national government employees who are to develop these analyses and managers who are to use these analyses in making commodity trade decisions. These audiences require different educational strategies.

A key element in any successful educational strategy is to have clear lines of responsibility for the development of risk assessments within each member country. Without the designation of specific individuals who will conduct such studies, it is impossible for any organization to provide the appropriate background and information. Only in member countries with such designation will there be the possibility for developing skills and knowledge to implement a harmonized approach to risk analysis.

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